

maintaining at least one sample population of the biological material in one of the following systems: an organ culture system; and an intact organism;

exposing the at least one sample population to a candidate optical contrast enhancing agent;

acquiring test data relating to one or more optical properties of the sample population subsequent to exposure to the candidate optical contrast enhancing agent; and

comparing the test data acquired to comparison data relating to the one or more optical properties of the sample population, whereby changes in the one or more optical properties reflected in the test data compared to the comparison data represent the optical contrast enhancing activity of said agent in said sample population and identify an agent that is useful for enhancing the sensitivity of optical detection in said population.

#### REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Following the above amendments, claims 2-9, 11 and 17 are pending, with claim 17 being in independent format. A request for a one month extension of time is being filed with this response.

#### **Amendment**

The title of the application as been amended as requested by the Examiner. Claim 10 has been cancelled from the application. Claim 17 has been amended to remove reference to cell culture systems and tissue culture systems. It is urged that none of this amendments constitute new matter.

#### **Claim Rejections**

Claims 2-4, 7, 11 and 17 stand rejected under 35 USC §102(b) as being anticipated by Nelson et al. (US Patent 5,169,944). This rejection is respectfully traversed.

Independent claim 17 of the present application is drawn to a method for identifying a contrasting enhancing agent useful for enhancing the sensitivity of optical detection of a biological material, wherein the method comprises acquiring test data relating to at least one optical property of a sample biological material. As stated on page 6, lines 6-8, of the

specification, such optical properties include light scattering, reflection, absorption, refraction, diffraction, birefringence, refractive index and Kerr effect.

In contrast, Nelson et al. disclose a method of delivering a contrast enhancing agent for use in hepatobiliary magnetic resonance imaging (MRI) of a subject. More specifically, Nelson et al. teach methods for altering NMR relaxation times by enterally administering a lipophilic contrast enhancing agent, thereby enhancing the MRI image. Such lipophilic contrast enhancing agents comprise a chelating ligand and a paramagnetic moiety. Magnetic resonance imaging does not measure or examine the optical properties of a material, rather it measures changes in the magnetic properties of the material. Thus Nelson et al. do not teach identifying novel optical contrast enhancing agents by obtaining test data relating to the optical properties of a material.

Applicants note that, for a reference to prior art under 35 USC §102, it must disclose every aspect of the claimed invention. It is submitted that Nelson et al. do not teach or suggest a feature of the present invention clearly recited in the pending claims, namely the measurement of optical properties, and that the rejection of claims 2-4, 7, 11 and 17 under 35 USC §102(b) as being anticipated by Nelson et al. may thus be properly withdrawn.

Claims 4, 9 and 17 stand rejected under 35 USC §102(b) as being anticipated by Turner (US Patent 4,812,412). This rejection is respectfully traversed.

Turner discloses and claims a method for preparing a standard biological specimen for use in evaluating the performance of tissue stains. In particular, Turner states that such standard specimens may be usefully employed in the quantitative evaluation of the performance of known stains and staining processes, wherein staining of a given biological sample is compared to that of the standard specimen. Such methods permit the calibration of known tissue staining and dyeing processes. Turner does not teach exposing a biological sample to a candidate contrast enhancing agent, for which the contrast enhancing properties are unknown, acquiring test data relating to at least one optical property of the sample, comparing such data with comparison data relating to the optical property of the sample, and thereby determining whether or not the candidate functions as a contrast enhancing agent, as recited in the present claims. Nor does Turner teach or suggest the use of organ culture systems or intact organisms as the biological sample, as recited in amended claim 17.

It is thus urged that the disclosure of Turner neither teaches nor suggests the inventive methods, and that this rejection of claims 4, 9 and 17 under 35 USC §102(b) may thus be properly withdrawn.

Claims 3-8, 10 and 17 stand rejected under 35 USC §102(e) as being anticipated by Poot et al. (US Patent 6,291,203 B1). This rejection is respectfully traversed in view of the above amendments and the following remarks.

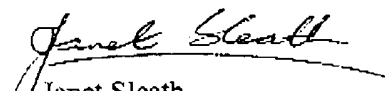
Poot et al. disclose unsymmetrical cyanine dyes and their use in staining mitochondria in culture cell lines. Poot et al. do not describe acquiring test data relating to at least one optical property of a biological sample selected from either organ culture systems or intact organisms in order to identify agents that are useful in enhancing the sensitivity of optical detection in the biological sample, as clearly recited in amended claim 17.

It is thus urged that Poot et al. do not teach or suggest the subject matter of the present claims and the rejection of claims 3-8, 10 and 17 under 35 USC §102(e) may be properly withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

Favorable reconsideration and allowance of the pending claims is respectfully requested.

Respectfully submitted,

  
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**SPECKMAN LAW GROUP**



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PATENT TRADEMARK OFFICE

48000.1002L

Application No. 09/326,244

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE SPECIFICATION:**

On pages 1 and 44 of the specification, the present title has been replaced with the following title:

--METHOD FOR IDENTIFYING OPTICAL CONTRAST ENHANCING AGENTS--

**IN THE CLAIMS:**

Claim 10 has been cancelled.

Claim 17 has been amended as follows:

17. (Three times amended) A method for identifying optical contrast enhancing agents useful for enhancing the sensitivity of optical detection of a biological material comprising:

maintaining at least one sample population of the biological material in one of the following systems: [a cell culture system; a tissue culture system;] an organ culture system; and an intact organism;

exposing the at least one sample population to a candidate optical contrast enhancing agent;

acquiring test data relating to one or more optical properties of the sample population subsequent to exposure to the candidate optical contrast enhancing agent; and

comparing the test data acquired to comparison data relating to the one or more optical properties of the sample population, whereby changes in the one or more optical properties reflected in the test data compared to the comparison data represent the optical contrast enhancing activity of said agent in said sample population and identify an agent that is useful for enhancing the sensitivity of optical detection in said population.